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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,566	02/19/2002	Audrey Goddard	P 2534-3	4737
9157	7590	06/14/2005	EXAMINER	
GENENTECH, INC. 1 DNA WAY SOUTH SAN FRANCISCO, CA 94080			JIANG, DONG	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,566

Applicant(s)

GODDARD ET AL.

Examiner

Dong Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,22,26-28 and 31-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31 is/are allowed.
- 6) ☒ Claim(s) 20,22,26-28 and 32-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicant's amendment filed on 14 March 2005 is acknowledged and entered. Following the amendment, claims 1-19, 21, 23-25, 29 and 30 are canceled, claims 20, 22, 26 and 28 are amended, and the new claims 31-36 are added.

Currently, claims 20, 22, 26-28 and 31-36 are pending and under consideration.

Withdrawal of Objections and Rejections:

All objections and rejections of claim 25 are moot as the applicant has canceled the claim.

The rejection of claims 20 and 26-28 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment.

The scope of enablement rejection, and lack of written description rejection of claims 26-28 under 35 U.S.C. 112, first paragraph are withdrawn in view of applicant's amendment.

The prior art rejection of claim 20 under 35 U.S.C. 102(e) as being anticipated by Timans (US6,680,380), is withdrawn in view of applicant's amendment.

Formal Matters:

Claim 33 is objected to for the following informalities, appropriate correction is required for each item:

In line 3 of the claim, the word "variant" is suggested to replace "variants".

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 22 and 26-28 remain rejected, and the new claim 33-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Timans, US6,680,380, for the reasons of record set forth in the last Office Action mailed on 27 September 2004, at page 6.

The teachings of Timans were reviewed in the last Office Action. Briefly, Timans discloses a human polypeptide of an IL-1 like molecule, which amino acid sequence (SEQ ID NO:4) comprises amino acids 35-203 of the present SEQ ID NO:5 with 100% sequence identity. Additionally, Timans teaches a fusion protein comprising the polypeptide and detection or purification tag including a FLAG, His6, or Ig sequence.

Applicants argument filed on 14 March 2005 has been fully considered, but is not deemed persuasive for reasons below.

At page 8 of the response, the applicant argues that the US patent '380 does not teach any specific or credible utility for SEQ ID NO:5, much less a specific and differential binding to IL-18R ECD but not IL-1R ECD, and thus applicants have isolated an operative and non-obvious fragment of the polypeptides disclosed in the patent. This argument is not persuasive because the art teaches that the polypeptide is IL-1 α , and that, like IL-1 α (now known as IL-18), said IL-1 α would stimulate production of IFN- γ by NK cells (column 47, the second paragraph). Further, more importantly, as Timans's polypeptide of SEQ ID NO:4 comprises amino acids 35-203 of the present SEQ ID NO:5 with 100% sequence identity, it is a polypeptide having or comprising amino acid sequence of residues 37 to 203 of the present SEQ ID NO:5 (as that in claims 22 and 33). Thus, the functional properties such as differential binding to IL-18R would be inherent for the Timans's polypeptide. In *In re Swinehart and Sfiligoj* ((CCPA), 169 USPQ 226, 1971), the Court held:

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“Mere recitation of newly discovered function or property, inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art; additionally”, where Patent Office has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may, in fact, be an inherent characteristic of prior art, it possesses authority to require applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on.”

In the instant case, Timans’s polypeptide meets the structural and sequence limitation of the claims, and the polypeptides having the same sequence would inherently have the same functional property regardless whether the prior art explicitly discloses that property.

With respect to the limitation of “variants thereof having 1 addition, deletion or conservative substitution” in claims 33-36, Timans teaches variants of the polypeptide, which have addition, deletion or conservative substitution (column 16, the second and the third paragraphs, and column 20, lines 42-51), and that random mutagenesis can be conducted at *a* target codon (column 16, lines 32-33). As such, the reference also anticipates claims 34-36.

Claims 20, 22 and 26-28 remain rejected, and the new claims 32-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Sims et al., US2003/0091532 A1, for the reasons of record set forth in the last Office Action mailed on 27 September 2004, at page 7.

The teachings of Sims were reviewed in the last Office Action. Briefly, Sims discloses a human IL-1 related polypeptide, IL-1 zeta, which amino acid sequence (SEQ ID NO:3) comprises amino acids 33-203 of the present SEQ ID NO:5 with 100% sequence identity. Additionally, Sims teaches a fusion protein comprising the polypeptide and Fc of an antibody.

Applicants argument filed on 14 March 2005 has been fully considered, but is not deemed persuasive for reasons below.

At page 8 of the response, the applicant argues that Sims does not teach any specific or credible utility for SEQ ID NO:5, much less a specific and differential binding to IL-18R ECD but not IL-1R ECD, and thus applicants have isolated an operative and non-obvious fragment of the polypeptides disclosed in the patent. This argument is not persuasive because Sims teaches that IL-1 zeta polypeptide induces TNF and IL-12 secretion, which is a specific or credible utility. Further, more importantly, as Sims’s IL-1 zeta of SEQ ID NO:3 comprises amino acids

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33-203 of the present SEQ ID NO:5 with 100% sequence identity, it is a polypeptide having or comprising amino acid sequence of residues 37 to 203 of the present SEQ ID NO:5 (as that in claims 22 and 33). Thus, the functional properties such as differential binding to IL-18R would be inherent for the Sims's polypeptide for the reasons addressed above.

With respect to the newly amended claim 20 and the new claim 32, the nucleic acid sequence of nucleotides 118-618 of SEQ ID NO:4 encodes the amino acid residues 37-203 of SEQ ID NO:5 (claim 20). Sims teaches that the polypeptide of IL-1 zeta of SEQ ID NO:3 includes a putative pro-domain extending from amino acids 1 to x, where x is an integer from 20 to 50. As such, the reference anticipates the fragment of residues 37-203 of the present SEQ ID NO:5 (claim 20), and the fragment of the polypeptide encoded by the cDNA clone of ATCC-203587, excluding the first 36 amino acids (claim 32).

With respect to the limitation of "variants thereof having 1 addition, deletion or conservative substitution" in claims 33-36, Sims teaches variants of the polypeptide, which have one or more deletions, insertions, or conservative substitutions (page 11, [0075] and [0076]). As such, the reference also anticipates claims 34-36.

Conclusion:

Claim 31 is allowable.

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Advisory Information:

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on 571-272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Dong Jiang, Ph.D.
Patent Examiner
AU1646
5/26/05